

**REMARKS**

Claims 1 to 51 are pending. Claims 10 and 15 to 51 have been withdrawn from consideration. Consequently, claims 1 to 9 and 11 to 14 are under consideration.

**§ 102 Rejections**

Claims 1 to 9 and 11 to 14 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 4,689,338 (“Gerster”). Applicants respectfully traverse the rejection.

Applicants submit that Gerster fails to teach an IRM compound attached to a macromolecular support material, as Applicants’ use the “attachment” of IRM compounds to a macromolecular support is described in their disclosure. The Office Action agrees with Applicants’ position, stating at page 3, “However the complexes as described by the specification with a support is not clearly taught in the prior art.”

The complete teaching of Gerster relied on in the Office Action is as follows:

The compounds of the invention are formulated for the various routes of administration in known, pharmaceutically [sic] accepted vehicles such as water or polyethylene glycol. (column 8, lines 21-24)

The Office Action states that the IRM compound could be hydrogen bonded to polyethylene glycol—a suitable macromolecular support material listed in Applicants’ disclosure—in the Gerster formulation. However, Applicants’ disclosure, at page 21, lines 10-13, specifically distinguishes the instant invention from the disclosure of Gerster:

The IRM is not simply dissolved or blended into a formulation from which it is to be released, but is attached to the support material by a sufficiently strong bond (which sometimes may require a covalent bond) so that under the circumstances of intended use the IRM is biologically active during use while it is attached to the support.

The Office Action responds that Applicants’ disclosure at page 21, lines 19-21 and states that the disclosure “clearly states that the IRM compound can be blended or mixed in.” However, the Office Action reads the cited passage out of context.

The passage does not refer to mere blending or mixing in a pharmaceutical vehicle, as taught in Gerster. Rather, the cited passage refers to an exemplary embodiment in which the IRM compound is blended or mixed into a macromolecular support material to form, for example, a

polymeric coating to which the IRM compound remains attached and biologically active for an intended period of time. The cited passage describes a single embodiment in a paragraph that provides details of various embodiments, each of which falls under the general description of the invention provided at page 21, lines 10-13, and quoted above: **the IRM is not simply dissolved or blended into a formulation.** This construction is wholly consistent with Applicants' description of the attachment of an IRM compound to a support material (page 8, line 28 through page 9, line 15) and distinguishes the present invention from the entirety of the teaching of Gerster upon which the rejection is based: merely formulating an IRM compound into a pharmaceutically acceptable vehicle.

Gerster fails to teach an IRM compound attached to a macromolecular support material, as Applicants use "attachment" at page 8, line 28 through page 9, line 15. Accordingly, the rejection of claims 1 to 10 and 11 to 14 under 35 USC § 102(b) as being anticipated by Gerster is improper and should be withdrawn.

### **§ 112 Rejections**

Claims 1-9 and 11 stand rejected under 35 USC § 112, first paragraph, as failing to enable a person skilled in the art to make and use the invention commensurate with the scope of the claims. The Office Action analyzes Applicants' specification under the factors enumerated in *in re Wands*. Applicants respectfully disagree with the analysis provided in the Office Action and submit that such an analysis favors a finding that Applicants' specification enables the full scope of the claimed subject matter.

1) Breadth of claims. The Office Action notes that the instant claims encompass complexes that include a broad variety of substrates. Applicants' specification does, indeed, identify a broad variety of *known* substrates. The substrates, their chemical reactive sites, and methods for attaching reactive moieties such as IRM compounds are all well known to those skilled in the art. Consequently, despite the apparent breadth of the claim scope, the existing knowledge in the art regarding the substrates favors enablement.

2) Nature of invention. The invention is an IRM-support complex in which the IRM moiety retains its biological activity after attachment to the support material. As noted above, the supports and methods of using the supports, generally, to form complexes are known. Also,

the biological activity and chemical relatedness of the IRM compounds, when free and non-complexed, are known. Thus, this factor slightly favors enablement or, at least, is neutral.

3) State of the prior art. As noted above, the substrates and the character of free IRM compounds are well known in the art. The Office Action acknowledges that the claimed complexes are not taught in the prior art. While, in isolation, this factor may weigh against enablement, any deficiency of teaching about the claimed complexes in the prior art is cured by Applicants' disclosure.

4) Level of ordinary skill. The Office Action acknowledges that those in the art are highly skilled. Thus, this factor favors enablement.

5) Level of predictability. The Office Action concludes that because the claimed complexes are not known in the prior art, there can be very little predictability. Applicants respectfully disagree. As noted above, the supports and the chemistry and biological activities of free IRM compounds are well known. Applicants have shown the manufacture of representative IRM-support complexes, thereby identifying reactive sites on the IRM compounds that can be used to form complexes while preserving at least a portion of the IRM compound's biological activity. Once provided with Applicants' disclosure, one skilled in the art can easily extrapolate from the exemplified complexes to non-exemplified complexes using (a) alternative known supports and/or (b) chemically and biologically related IRM compounds. The chemical similarity (see page 32, Reaction Scheme I; and page 34, lines 12-20) of the IRM compounds makes the manufacture of non-exemplified IRM-support complexes utterly predictable. Consequently, this factor favors enablement.

6) Amount of direction. The Office Action states that the specification merely names various supports in a large list. Applicants respectfully disagree. Applicants do, indeed, provide a list of suitable known support materials. In each case, the chemistry of the support material is well known in the art. Applicants also, provide detailed direction for attaching the IRM compound to the support so that the IRM compound retains its biological activity (page 27, line 18 through page 34, line 20). Thus, this factor also favors enablement.

7) Working Examples. The Office Action asserts that the specification does not have any working example. Applicants respectfully disagree. Applicants have provided 32 examples of making IRM-support complexes by various methods using a variety of support materials.

Applicants also provide test data showing that the IRM biological activity from different complexes. Again, this factor favors enablement.

8) Experimentation necessary. The Office Action asserts that, due to a lack of working examples, the quantity of experimentation required for one skilled in the art to make and use the full scope of the claimed invention is “very high and burdensome.” As noted above, however, Applicants have, in fact, provided ample working examples and additional direction, coupled with a high degree of predictability. One skilled in the art, following Applicants’ direction and working examples, and using the knowledge of support materials and the IRM compounds known to those skilled in the art, would require little or no experimentation to make and use the full scope of the claims. This factor, too, favors enablement.

Thus, the analysis of Applicants’ disclosure under the factors of *In re Wands* shows that most factors favor enablement; one factor may be, at worst, neutral; and the one factor that may weigh against enablement, is cured by the teaching of Applicants’ disclosure.

Applicants therefore submit that the rejection of claims 1-9 and 11 under 35 USC § 112, first paragraph, is made in error, and that the rejection should be withdrawn.

### **CONCLUSION**

In view of the above, it is submitted that the application is in condition for allowance. Reconsideration of the application is requested.

Allowance of claims 1-10 and 11-14 at an early date is solicited.

Respectfully submitted,

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